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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/900,559	07/25/1997	SHU-CHING CHENG	226/242	8245

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LYON & LYON LLP
633 WEST FIFTH STREET
SUITE 4700
LOS ANGELES, CA 90071

EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/900,559

Applicant(s)

CHENG ET AL

Examiner

Ja-Na A Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawing corrections will not be held in abeyance. Applicants must submit proposed drawing corrections in response to the requirement in the Office action.

Response to Arguments

2. Applicant's arguments filed April 5, 2002 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The rejection of claims 10-11, 13-15 and 17-21 under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., in view of Hochstrasser (US Patent 4,059,407) is maintained. Applicants argue that Imrich fails to provide an assay chamber that is physically separate from the lateral flow device, and fails to describe inserting the device into a separate sample chamber. However, Imrich et al., teach a component that contains two plastic removable pieces, the top piece contains the sample-processing feature and the bottom piece is used for strip placement. Thus Imrich et al., teach a physically separate chamber, since applicant defines the lateral flow device as comprising a sample receiving region and detection region, i.e., Imrich et al's device

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where the strip is placed and the upper component is a separate piece; while Hochstrasser teach the immersion of sample receiving region into is well known in the art as a mode of contacting the sample receiving region with extracted sample.

Applicants argues that Imrich does not state that filters may be used to stop the flow of extracted sample whereas the claims require that fluid is not in communication with the device prior to insertion, however as stated above, Imrich teach two separate pieces, the assay chamber and the test strip device.

Applicants argue that Imrich does not explicitly describe or suggest a method for detecting a Strep A antigen where the assay chamber is separated from the immuno-device and that Hochstrasser does not teach such construction. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). However, as stated above Imrich teach such separation and Hochstrasser further adds that such devices can operate by immersion with the same components as those utilized by Imrich's device and separate chamber. Thus, applicants' argument is not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

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references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been prima facie obvious to modify the method of determining the presence or absence of Strep A antigen in a sample comprising the using of a lateral flow immunochromatographic device comprising a sample region and detection region using the claimed reagents, wherein the antigen was extracted from the sample and inserted in the sample receiving region to determining the presence or absence of said antigen as taught by Imrich wherein the modification consist of inserting the sample receiving region into a separate chamber as to allow contact of the sample as taught by Hochstrasser. One would have a reasonable expectation of success since the prior art teach as inserting a sample region into a separate assay chamber to allow contact between the sample and device. Moreover, no more then routine skill would have been required to use a device that comprises a support member, a plurality of indicating agents and separate zones comprising many of the same components as included in the device of Imrich, when such device is known to be useable with any biological fluid and use a functionally equivalent method of contacting the sample with the device.

Applicants argue that the bulk of plastic casing of Imrich would make immersion difficult if not impossible, however no more then routine skill is required to use an assay chamber of any size, i.e., one that would fit the device of Imrich. Moreover Imrich already teaches two physically separate components, such that the size of the device is not at issue.

Applicants argue that the device of Imrich would be inconsistent with any convenience afforded by combining the sample chamber and test strip into one place housing and teaches away from immersing the test sample into a separate chamber following extraction. However, as stated above, no more than routine skill would have been required to use a device that comprises a support member, a plurality of indicating agents and separate zones as included in the device of Imrich, when such test strip devices are well known in the art as being immersable. Imrich et al., does not state that there is only one way to contact the sample and test strip, when Imrich teach that test strip component as separate. One would have a reasonable expectation of success in using a test device inserted into a separate assay chamber to allow contact between the sample and device when the prior art already teach such use.

Applicants argue the commercial success of the claimed device because of its increased sensitivity, wherein applicant refers to bulky housing, however the claim does not limit the size of the housing, thus this argument is not persuasive. Applicant's declaration claims that the device of Imrich requires that the test be performed by more qualified licensed personnel, however the level of qualification is not a limitation of the claim and is a subjective assessment made by applicants with any scientific support. Applicant argues that a finding of non-obviousness is proper where there is evidence of commercial success of a product having as a critical feature, however applicants mere statements of commercial success is not sufficient as substantial evidence of commercial success. Applicant has failed to provide any financial data of such request,

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an abundance of order request or any form of evidence as proof of such success.

Therefore, applicants' arguments are not persuasive.

4. The rejection of claims 12 and 16 under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., and Hochstrasser as applied to claim 10 above, and further in view of Bogart et al., is maintained. Imrich et al., and Hochstrasser have been previously discussed, however neither teaches the vigorous mixing or an extraction solution where the additions of the extraction materials are of similar concentrations. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been prima facie obvious at the time of applicants' invention to modify the method of determining the presence or absence of Strep A antigen in order to optimize the experimental parameters and reagents of the method of Imrich et al., and Hochstrasser by selecting conventional components for generating nitrous acid and times of extraction as taught where the general conditions of a claim are disclosed in the prior art as taught by Bogart et al. One would have a reasonable expectation of success when Imrich already teach the need and several well known reagents required to extract the Strep A antigen and

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Bogart teach the optimization of such reagents. Moreover, no more than routine skill would have been required to discover the optimum or workable ranges taught by Bogart; optimizing concentrations of reagents in a method already known in the art as being useful for such has not been patentable even when the concentrations creates results been then expected, but does not produce unexpected results. Thus, applicants' arguments are not persuasive.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 
July 19, 2002


MARK NAVARRO
PRIMARY EXAMINER